



ISMPP University

The program will begin promptly at 11am EDT

October 25, 2017





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ISMPP Announcements

- **REGISTRATION NOW OPEN!** 2018 European Meeting of ISMPP, *Advancing Medical Publications in a Complex Evidence Ecosystem* January 23-24 in London
- The ISMPP U Committee wants to hear from you! Groups or individual members can submit topic ideas via the ISMPP U proposal form located on the ISMPP U Committee page: <http://www.ismpp.org/ismppu>



For Your Best ISMPP U Experience...

To optimize your webinar experience today:

- Use a hardwired connection if available
- Use the fastest internet connection available to you
- If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers



Questions

- To ask a question, please type your query into the Q&A box
 - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, **"ALL Panelists"** Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions

1. Click on the question mark to view the Q&A box

2. Type your question into the Q&A box and SEND

NOTE: Make sure you send your question to "ALL Panelists"

The screenshot shows the Zoom interface with the Q&A panel open. The 'Participants' panel at the top shows 'Speaking: Lisa Klos (Host, me)' and 'Attendee: 0'. The 'Chat' panel is empty. The 'Q&A' panel shows a question from 'Laine Capaccio' at 10:22 AM: 'Q: can you see my q&a?'. The 'Send to' dropdown menu is set to 'All Participants'. The 'Send' button is visible.



Introductions

FACULTY: **Theodora (Theo) Bloom** is executive editor of *The BMJ* (since 2014) and was European Coordinator for the 8th Peer Review Congress. At *The BMJ* her responsibilities include operations in print and online, as well as ethical and policy matters. She has worked in biomedical publishing since 1992, initially as an editor on the biology team at *Nature*, and then on the founding team of *Current Biology*. After a number of years helping to develop *Current Biology* and its siblings *Structure* and *Chemistry & Biology*, Theo joined the beginnings of the open access movement. As the founding editor of *Genome Biology* she was closely involved in the birth of the commercial open access publisher BioMed Central, where she remained for several years, ultimately as Editorial Director for *Biology*. After a spell as a freelance publishing consultant working with a variety of clients, including a medical communications agency, she joined the non-profit open access publisher Public Library of Science (PLOS) in 2008, first as chief editor of PLOS Biology and later as Biology Editorial Director with additional responsibility for PLOS Computational Biology and PLOS Genetics. She also took the lead for PLOS on issues around data access and availability. She chairs the scientific advisory board for EMBL-EBI Literature Services. Until recently she served on the boards of NAM Publications and the Dryad digital repository, and on the Genome Canada Data Sharing Policies Advisory Committee.

Theo has a bachelor's degree in Natural Sciences and a PhD in developmental cell biology from the University of Cambridge and worked as a postdoctoral fellow at Harvard Medical School, researching cell-cycle regulation, before moving into publishing.



Introductions

FACULTY: Jackie Marchington is Director of Global Operations at Caudex, a McCann Health Company. Jackie joined Caudex in 1990 as a medical editor/writer following a period of post-doctoral research. Since then, she has developed within the company in a range of roles culminating in her current position of Director of Global Operations. During her 25+ years in healthcare communications, she has used her logical approach to problem-solving and project development to evolve the current operating, quality and ethical standards for which Caudex is known.

She develops and delivers both internal and external training on all aspects of medical publications, including publication ethics, compliance and copyright, and works with all Caudex offices to ensure understanding of and adherence to quality control protocols, as well as processes that contribute to the smooth and efficient development of projects. Jackie became a CMPP in 2011, is an active ISMPP committee member (Advocacy and Outreach) and is a member of the Global Alliance of Publication Professionals (GAPP) team, a volunteer group who provide timely and credible responses to influential stories about medical publication professionals (eg, professional medical writers, publication planners).



Introductions

MODERATOR: Lisa Baker is a freelance medical writer. She was previously a Medical Director at inScience Communications, Springer Healthcare, and a Scientific Team Lead at Envision Pharma Group. Lisa's work has included publication development and strategic publication planning for varied clients and therapeutic areas. Lisa received her PhD in research psychology from McGill University. She is an ISMPP Certified Medical Publication Professional™ (CMPP) and is the current chair of the ISMPP U Committee.



Learning Objectives

At the end of this presentation attendees should be able to:

- Have an increased awareness of the latest issues surrounding peer review and scientific publications
- Have a summary of the key takeaways from the Eighth International Congress on Peer Review and Scientific Publication
- Be familiar with the implications for publications professionals of the topics discussed at the Peer Review Congress



Disclaimer

Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP



Theo Bloom



Declaration of interests

- I am currently Executive Editor of *The BMJ*, published by BMJ, a wholly owned subsidiary of the British Medical Association
- *The BMJ* is co-organizer of the Peer Review Congress, and I was European Coordinator this year.
 - I previously worked for PLOS, 2008-2014
 - Current voluntary role: EBI/Literature Services/EuropePMC Advisory Board
 - I'm solely responsible for today's content



What I'll talk about today

- From the perspective of a journal editor
- Some work from colleagues and former colleagues
- Most credit to Hilda Bastian, and the twitterati



<http://blogs.plos.org/absolutely-maybe>



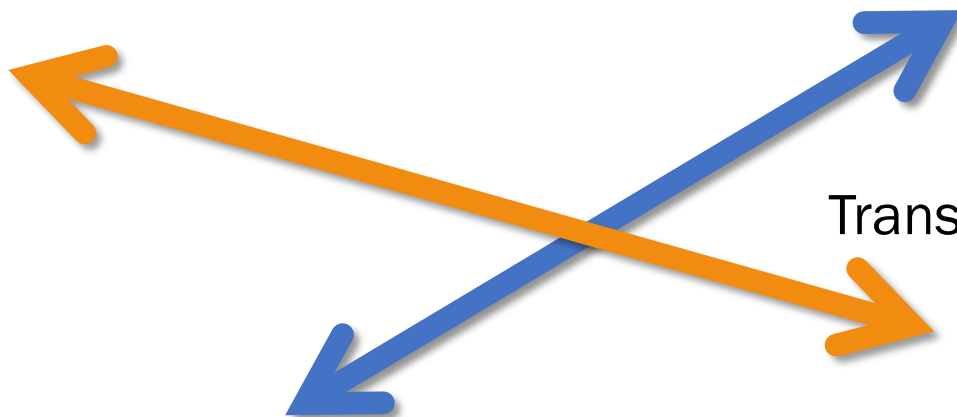


Key disagreements at the Congress

Should publication be ...?

Single- double- or triple-blind

Rapid / immediate



Transparent and open

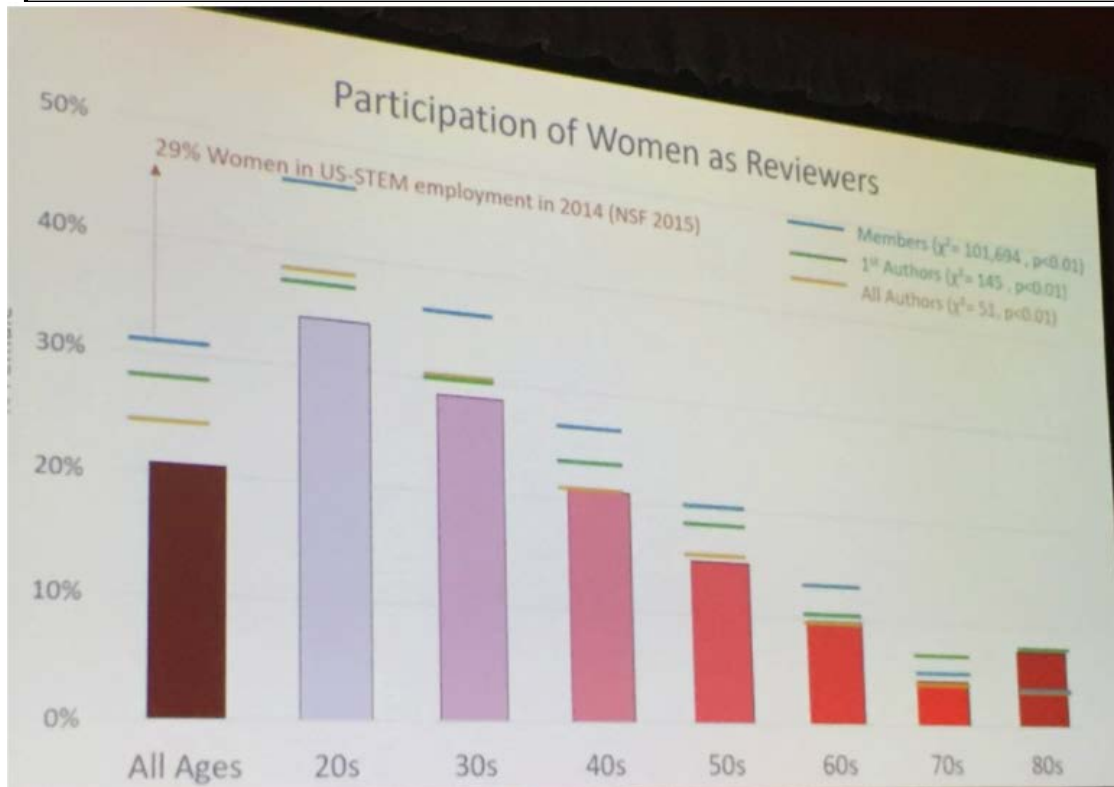
Slow and careful



Biases in reporting and in peer review

What types of bias?

Bias #1: Gender




Jory Lerback and
Brooks Hansen.
American Geophysical Union



Bias #2: Spin

| Definition | n = 35 | Exam |
|---|-------------|--|
| Reporting practices that distort the interpretation of results and create misleading conclusions, suggesting a more favourable result | 20 (57%) | 'Spec exper differ nons 'We d spinn the m expla |
| Discordance between results and their interpretation, with the interpretation more favourable than the results | 9 (26%) | '...w concl |
| Attribution of causality when study design does not support it | 3 (9%) | 'Inap one b [15] |
| Overinterpretation or inappropriate extrapolation of results | 3 (9%) | 'We d that n |

<https://doi.org/10.1371/journal.pbio.2002173.t002>



Scott LeMaire
 @scottlemaire

Follow

To be avoided when writing papers: common types of problematic spin in scientific publications as studied by Quinn Grundy et al. #PRC8

Practices used to spin results

- Inappropriate claims given study design
- Inappropriate recommendations for practice
- Selective reporting within the text
- Results presented more favourably than warranted

Chiu K, Grundy Q, Bero L (2017) 'Spin' in published biomedical literature: A methodological systematic review. PLoS Biol15(9): e2002173. <https://doi.org/10.1371/journal.pbio.2002173>



Bias #3: Interim results



Magne Nylenna

@magnenylenna

Follow



Be aware of interim results of randomized trials, says Steven Woloshin #PRC8

Summary

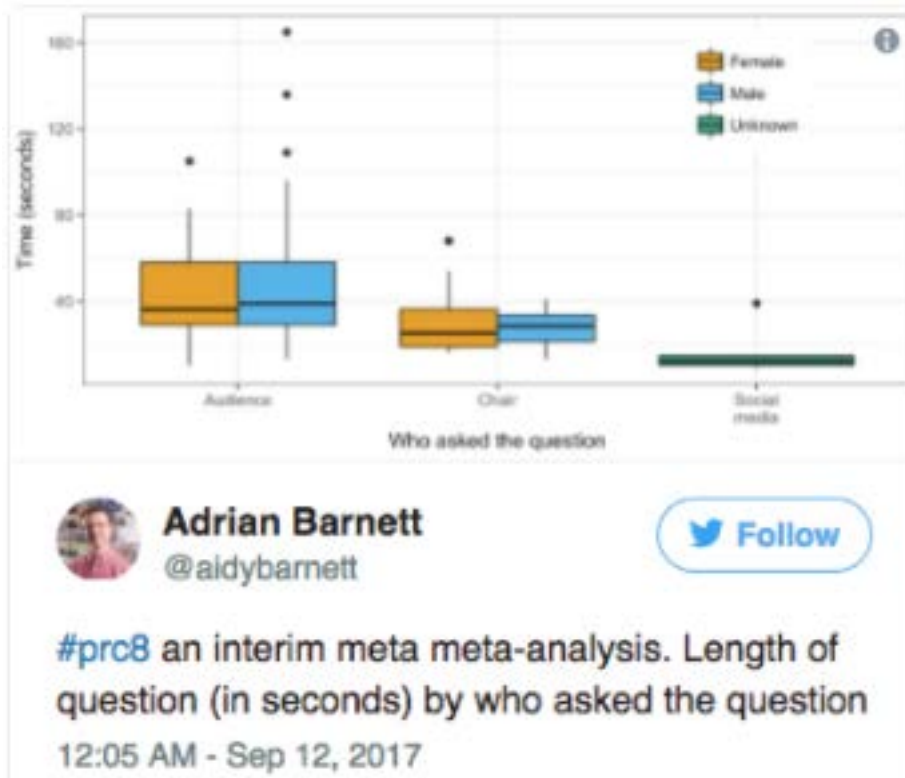
Many interim publications report analyses that are not pre-specified or lack a compelling justification.

Frequent nonpublication may cause bias since final treatment effects remain unknown.

Interim and final publications have similar journal and media prominence but conclusions may change.



Bias #3: Interim results



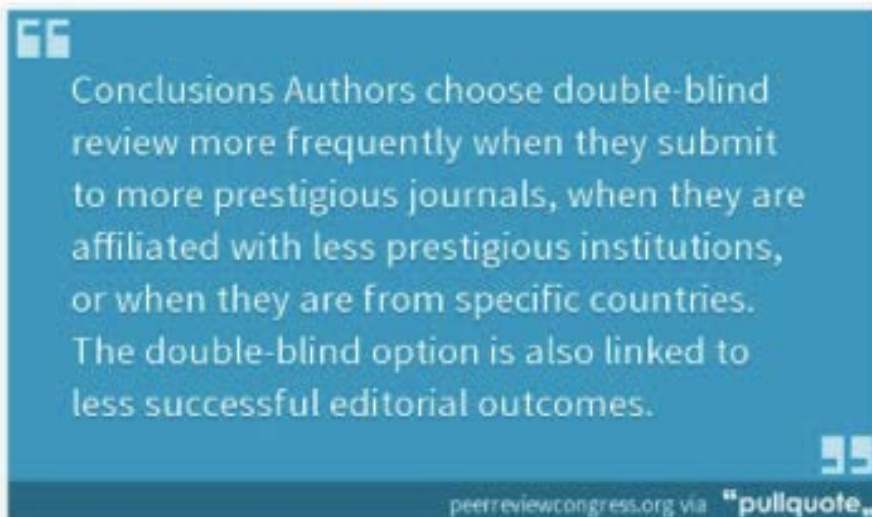


Fixing peer review

Blinding versus anonymity



Fixing peer review #1 – double-blind



Elisa De Ranieri, Springer-Nature

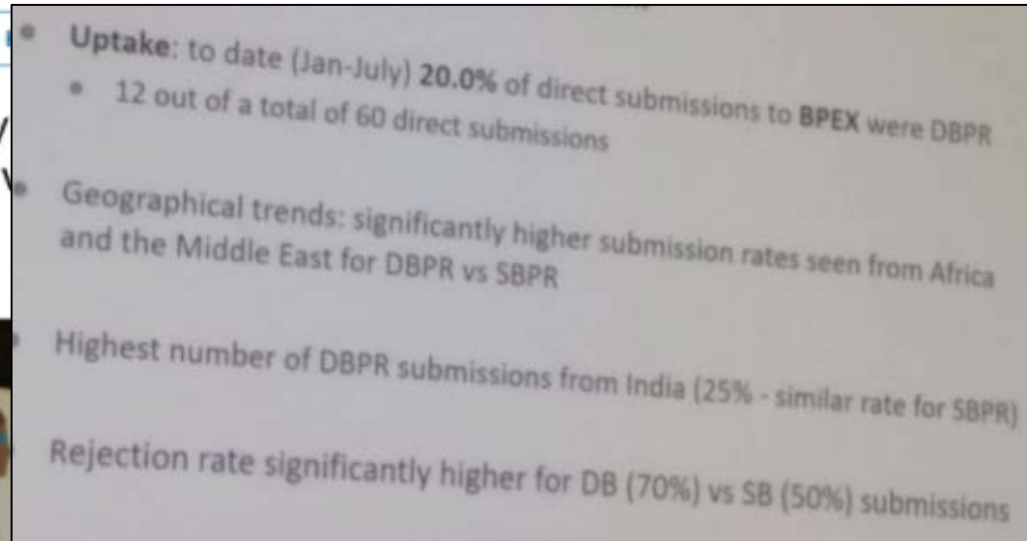
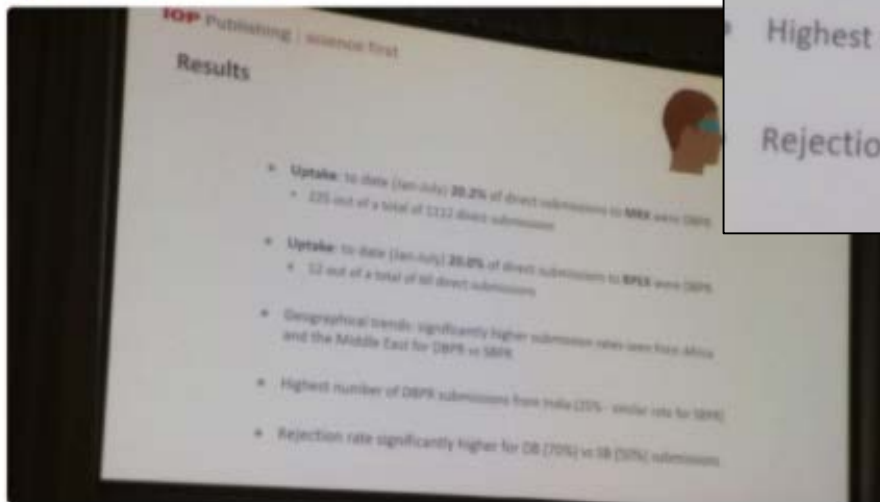
Fixing peer review #2 – double-blind



Editage Insights

@Editage

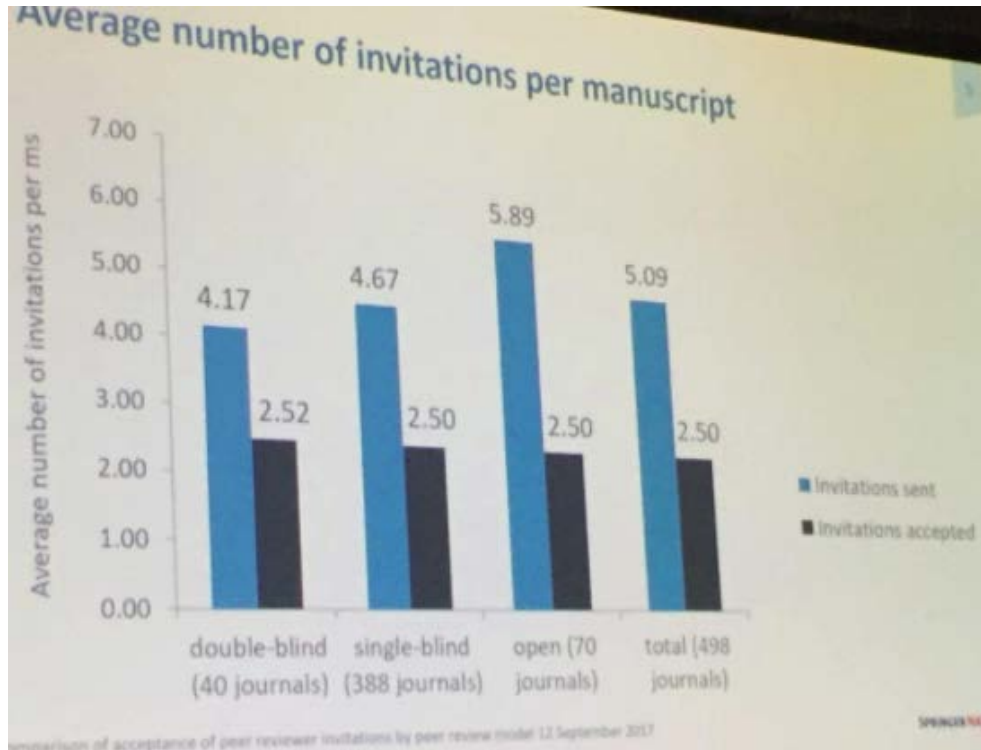
Harris shares @IOPPublishing survey
#Author preference for Double blind v
Single blind #peerreview #PRC8
#peerrevwk17



Simon Harris, IOP Publishing

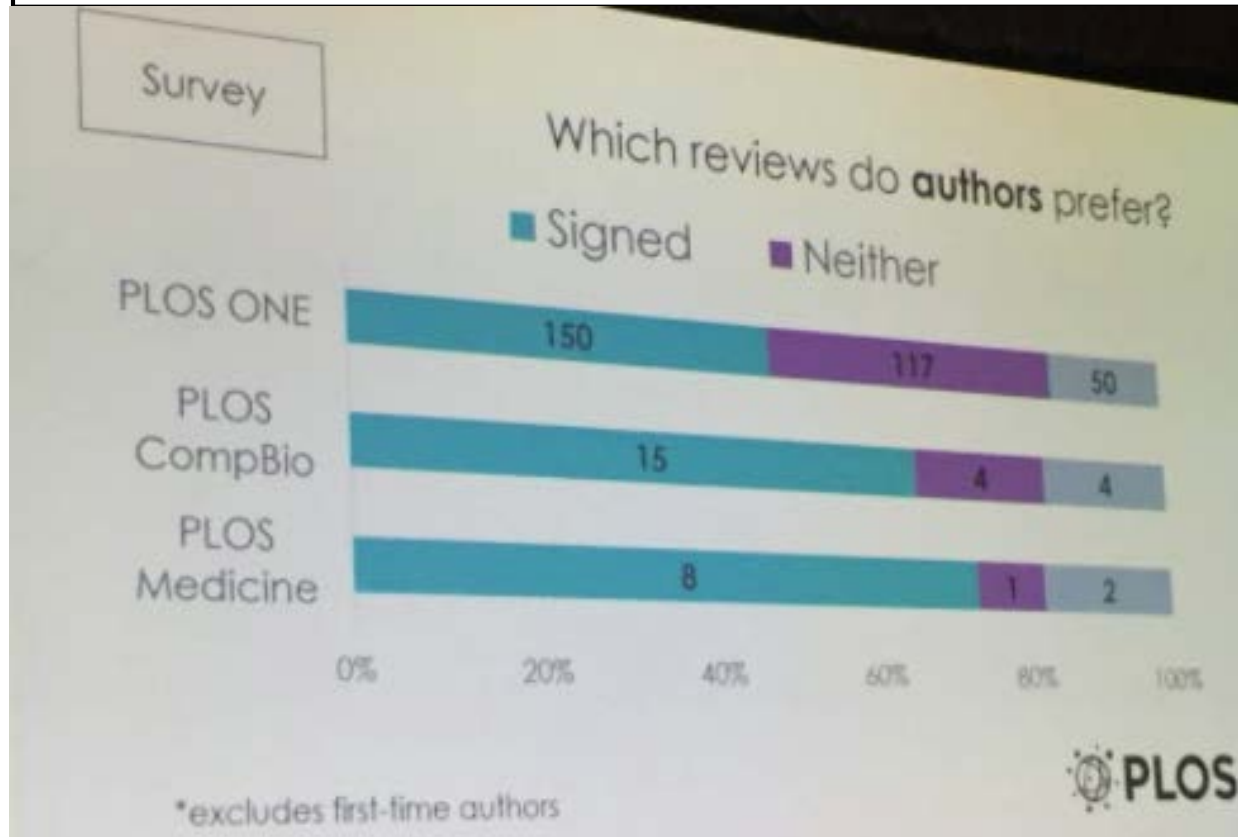


Fixing peer review #3 – signed reviews



Maria Kowalczyk, BMC

Fixing peer review #4 – signed reviews²



Elizabeth Seiver, Helen Atkins
PLOS



Fixing peer review #5



Hilda Bastian

<http://blogs.plos.org/absolutely-maybe/2015/05/13/weighing-up-anonymity-andopenness-in-publication-peer-review/>



Fixing reporting

Checklists



Improving reporting #1 - checklists

A core set of reporting standards for rigorous study design

Randomization

- Animals should be assigned randomly to the various experimental groups, and the method of randomization reported.
- Data should be collected and processed randomly or appropriately blocked.

Blinding

- Allocation concealment: the investigator should be unaware of the group to which the next animal taken from a cage will be allocated.
- Blinded conduct of the experiment: animal caretakers and investigators conducting the experiments should be blinded to the allocation sequence.
- Blinded assessment of outcome: investigators assessing, measuring or quantifying experimental outcomes should be blinded to the intervention.

Sample-size estimation

- An appropriate sample size should be computed when the study is being designed and the statistical method of computation reported.
- Statistical methods that take into account multiple evaluations of the data should be used when an interim evaluation is carried out.

Data handling

- Rules for stopping data collection should be defined in advance.
- Criteria for inclusion and exclusion of data should be established prospectively.
- How outliers will be defined and handled should be decided when the experiment is being designed, and any data removed before analysis should be reported.
- The primary end point should be prospectively selected. If multiple end points are to be assessed, then appropriate statistical corrections should be applied.
- Investigators should report on data missing because of attrition or exclusion.
- Pseudo replicate issues need to be considered during study design and analysis.
- Investigators should report how often a particular experiment was performed and whether results were substantiated by repetition under a range of conditions.

Malcolm Macleod

Landis et al. Nature 490, 187–191

doi:10.1038/nature11556



Improving reporting #1 - checklists

Findings of a retrospective, controlled cohort study of the impact of a change in Nature journals' editorial policy for life sciences research on the completeness of reporting study design and execution

Malcolm Robert Macleod, The NPQIP Collaborative group

doi: <https://doi.org/10.1101/187145>

This article is a preprint and has not been peer-reviewed [what does this mean?]

Abstract Info/History Metrics Supplementary material Preview PDF

Abstract

Objective: To determine whether a change in editorial policy, including the implementation of a checklist, has been associated with improved reporting of measures which might reduce the risk of bias. **Methods:** The study protocol has been published at DOI: 10.1007/s11192-016-1964-8. **Design:** Observational cohort study. **Population:** Articles describing research in the life sciences published in Nature journals, submitted after May 1st 2013. **Intervention:** Mandatory completion of a checklist at the point of manuscript revision. **Comparators:** (1) Articles describing research in the life sciences published in Nature journals, submitted before May 2013; (2) Similar articles in other journals matched for date and topic. **Primary Outcome:**

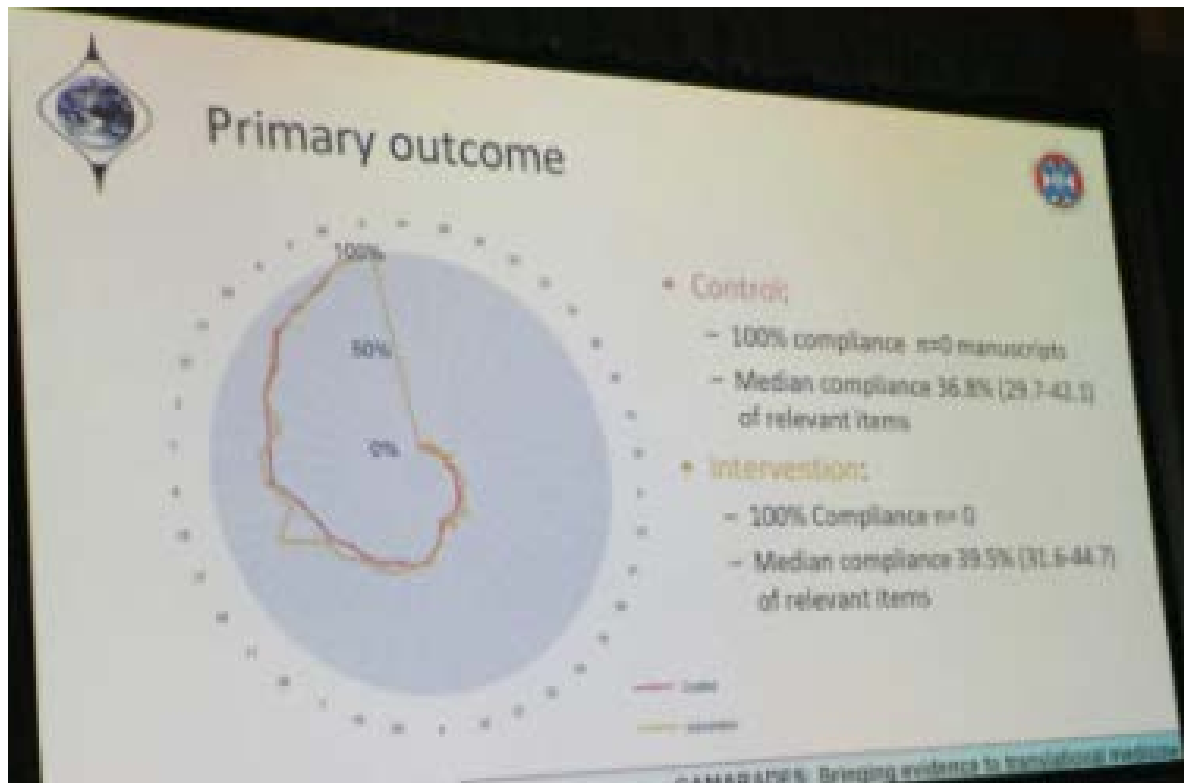


Cold
Spring
Harbor
Laboratory

bioRxiv
beta
THE PREPRINT SERVER FOR BIOLOGY



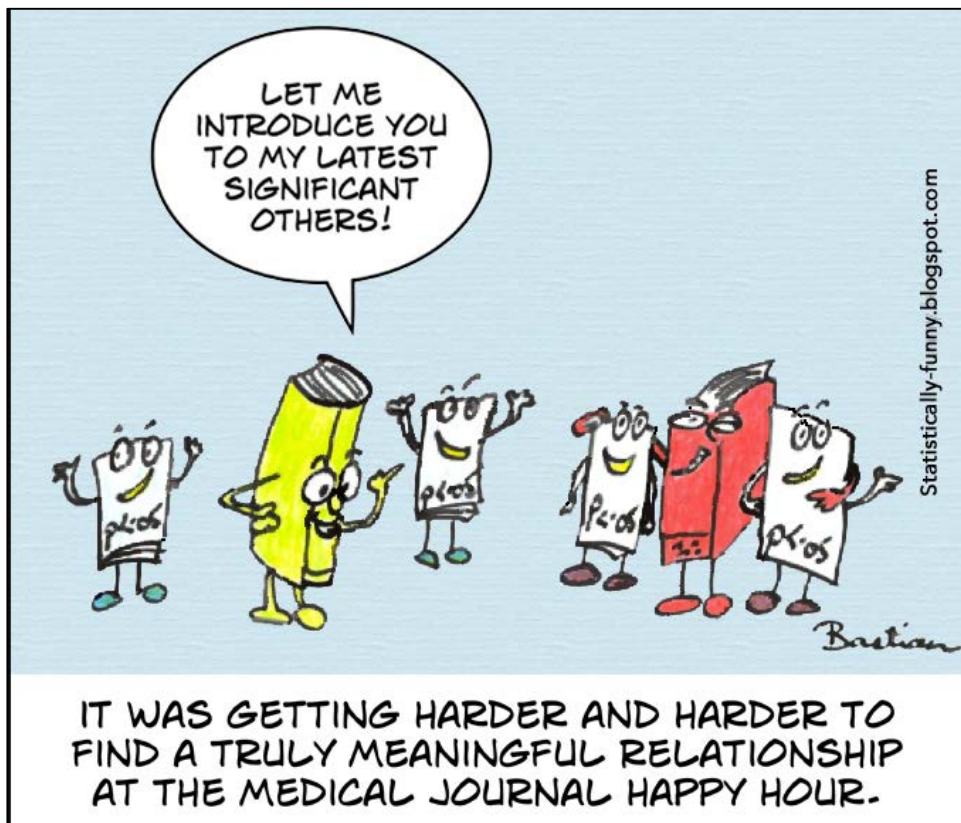
Improving reporting #2 – checklists²



Emily Sena,

Edinburgh

Improving reporting #3





Improving reporting #4 – speeding up



Harlan Krumholz

@hmskyaie

Following

Coming ...preprint server for medicine.
Accelerate research, complement peer
review, encourage sharing. @MedArXiv
@YODAProject w/@OSFramework



5:23 PM - 5 Sep 2017



Reasons to be cheerful?

Should we be optimistic or pessimistic?



Pessimism #1

- “There seems to be no study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, too obscure, and too contradictory, no analysis too self-serving, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print”

Drummond Rennie,

quoted by David Moher



Pessimism #2

Special Communications

Statistical Evaluation of Medical Journal Manuscripts

Stanley Scher, PhD, and Irving Karlen, MA

Contributors of scientific communications to medical journals are responsible for the research designs of their studies, the applicability of the statistical tests used, and the validity of the

to differences in the numbers of articles evaluated in each journal.

Each communication was subjected to an abbreviated but intensive critical reading by a com-

Steve Goodman,

JAMA. 1966 Mar

28;195(13):1123-8.

Some Optimism? – COI declarations



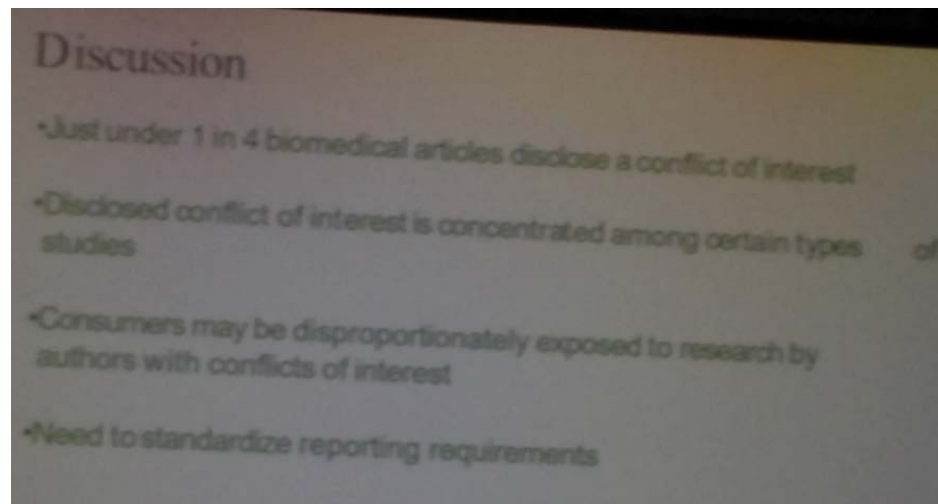
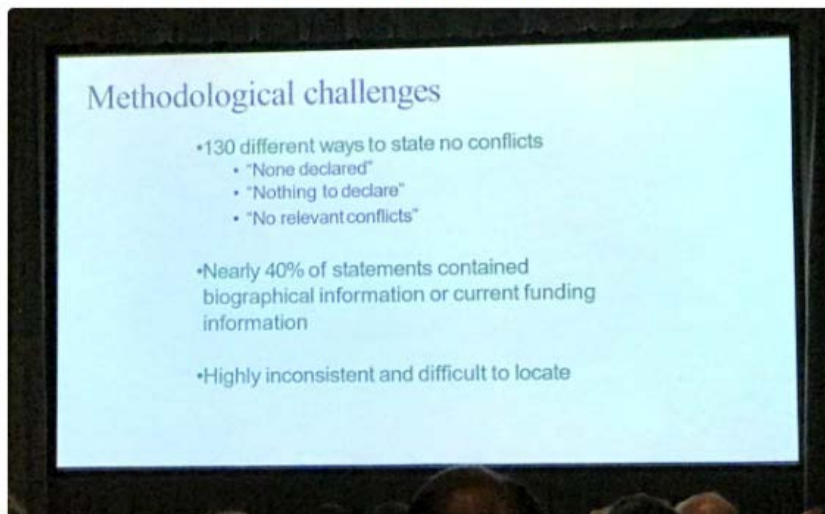
Alexandra Winter

@alexandralw2

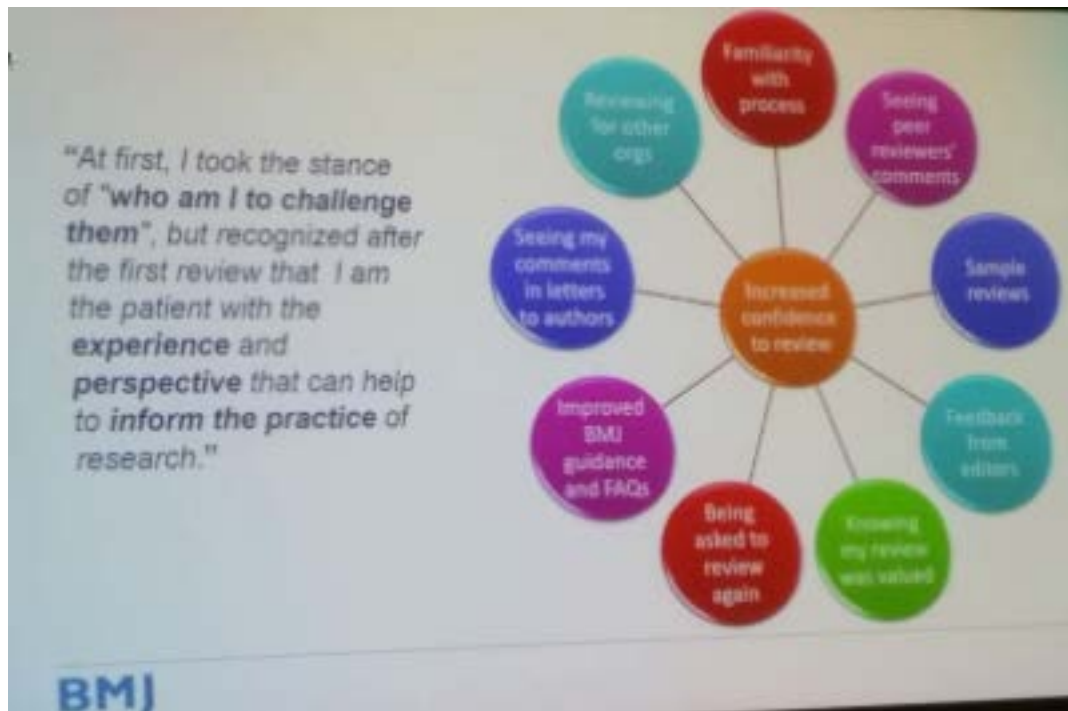
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..Considerable methodological challenges to studying author conflict of interest Quinn Grundy [@peerrevcongress](#) [#Prc8](#)



Optimism #2 – patient involvement



Sara Schroter, BMJ

Optimism #3 – patient involvement



Alice Meadows

@alicejmeadows

Following

Fascinating approach to peer review of @PCORI grants involving patients/carers/advocates, stakeholders (eg insurers) AND scientists #PRC8

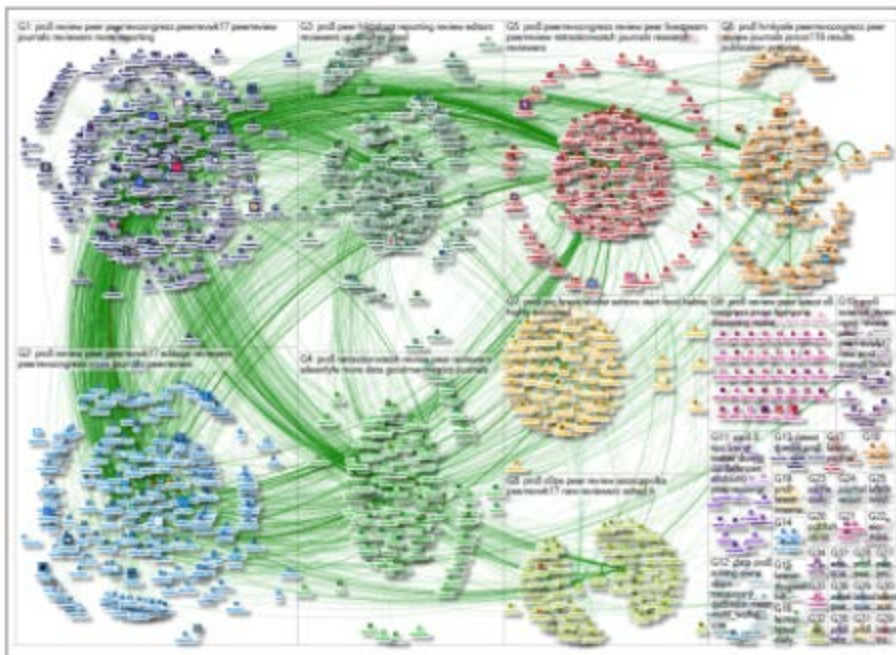
PCORI Merit Review Criteria and Reviewers

| | Scientists | Patients | Other Stakeholders |
|--|------------|----------|--------------------|
| Impact of the condition on the health of individuals and populations | ★ | | |
| Potential to improve health care and outcomes | ★ | ★ | ★ |
| Technical Merit | ★ | | |
| Patient-centeredness | ★ | ★ | ★ |
| Engagement with Patients and stakeholders | ★ | ★ | ★ |



Laura Forsythe, PCORI

Optimism #4 – network of research



#prc8 Twitter NodeXL SNA Map and Report for Sunday, 10 September 2017 at..

The graph represents a network of 411 Twitter users whose recent tweets contained "#prc8", or who were replied to or mentioned in those tweets, taken from a data set

nodexigallery.org

Graham Mackenzie

@gmacscotland Follows you

Optimism #5 – humour



"The difference between medical research and agricultural research is that medical research is done by doctors but agricultural research is not done by farmers."

Attributed to M. Healy in D. Altman, SIM, 1998



Thanks for listening!



@TheoBloom
@bmj_latest



Jackie Marchington



Disclosures

- The opinions expressed in this webinar are mine, and do not necessarily reflect those of my employer
- My employer paid for my registration and subsistence costs to attend the peer review congress, mainly to stop my unseemly pleading



As a newbie...

- Similar size and feel to ISMPP EU meeting
- Not the usual publishers (companies) we meet at ISMPP
- Small exhibition, 16 exhibitors
 - Data/analytics
 - Workflow/back office
 - Peer review management
 - Editorial services
 - EQUATOR



Connected

- All non-keynotes research based
- Live streamed on Facebook
- Active Twitter participation
 - Questions via Twitter
- Queues at the microphones
- Simultaneous publications
- Ran pretty much to time



Jackie Marchington @blazingocelots · Sep 11

Love it that a question from the floor has just lead to a potential research collaboration! #PRC8

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Bias associated with conflict of interest and peer review

Focusing on industry (me, not the agenda!)



Introductory keynote

- COIs
 - information overload
- Bias
 - Methods/research questions
 - Unpublished studies/ selective reporting
 - Analysis
 - Interpretation “spin”



Jackie Marchington @blazingocelots · Sep 10

The two biggest unresolved problems in the literature are bias and spin according to Lisa Bero at [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Disclosure of financial ties is insufficient to describe conflicts of interest. Often, it's just too much information [#prc8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Lisa Bero is kicking off [#prc8](#) talking about bias in the research. Research design, reporting, interpretation and analysis are all culprits

[View Tweet activity](#)



Stopping spin

- Checklist for peer reviewers
- Peer review methods and results (including supp info)



Jackie Marchington @blazingocelots · Sep 10

Interesting that Lisa Bero states that editors and peer reviewers can add spin through their comments [#prc8](#)

[View Tweet activity](#)

- Eliminate author discussion section
- Post-publication discussion
 - Multiple discussions
 - Megaphone effect (social media)



Conflict of interest statements

COIs are confusing

- 130 different ways of stating no conflicts of interest!
- Conclusion: Conflict of interest statements should be standardized
 - No mention of ICMJE form
 - No mention of CONVEY global disclosure system



Jackie Marchington @blazingocelots · Sep 10

Call for standardisation of COI disclosures from Quinn Grundy, and for author COI to be separate from article COI. Would CONVEY help? [#prc8](#)

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Industry bias in systematic reviews

Systematic reviews with industry funded authors are biased

- Study of studies about systematic review bias
 - Methodological quality similar
 - Statistically favourable results frequency similar
 - Financial COI = more favourable conclusions
- Unclear whether funding impacts *results* of systematic reviews



Study registration: missing studies

Do missing trials affect the conclusions of systematic reviews?

- Including additional trials found only on CT.gov made no difference to the strength of evidence or conclusions of systematic reviews in 5 clinical areas
- Suggested reasons for this include:
 - few of the additional studies included results
 - outcomes were mismatched between registry and paper



Interim results

- Of 171 papers reporting interim results, only 40% were prespecified
- For studies >1 year past completion date (158/171)
 - only 57% were fully (finally) reported
 - 85% of abstract conclusions did not change
- Journals should only report **prespecified** interim data sets and commit to **publishing full results** on trial completion



Jackie Marchington @blazingocelots · Sep 10

Would journals be willing to link interim to final papers if the final paper was published in another journal? [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Of 171 papers of interim results, only 40% were specified in the protocol. 72 paper pairs with interim and final results were found [#PRC8](#)

[View Tweet activity](#)



Spin

- Study of “spin” studies...
 - Studies more prevalent in trials
 - Spin more prevalent in trials
 - Spin not associated with industry funding

Design: “We had sufficient data to[...]analyse the association of industry sponsorship[...]with spin”

Results: “However, the meta-analysis found no significant association, possibly owing to the heterogeneity of the 7 included articles”



Jackie Marchington @blazingocelots · Sep 10

Interesting that the questioner assumes the finding of the lack of industry funding bias is a negative result. #PRC8

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Results of this meta-analysis show "Industry sponsored studies are no more likely to have spin than non-industry sponsored studies" #PRC8

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Four main categories of "spin": inappropriate claims, inappropriate recommendations, selective reporting, overextrapolation #PRC8

[View Tweet activity](#)



Data sharing: academia

- Survey of clinical trial authors
- About half had a plan and about a third had received requests
- Happy for inclusion in meta analyses, less so for replication
- 3–125 hours to prepare data set



Jackie Marchington @blazingocelots · Sep 10

Q: Is reluctance to share data for similar analyses driven by the original authors not having thought of the proposed analysis? [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Would data sharing at the time of publication offset any costs of going back to prepare data retrospectively? [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Q: had authors received funding to support data sharing? We'll have to wait for the final publication to find out! [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 10

Authors are more willing to share data for meta-analyses (96%) than for replication studies (73%) [#PRC8](#)

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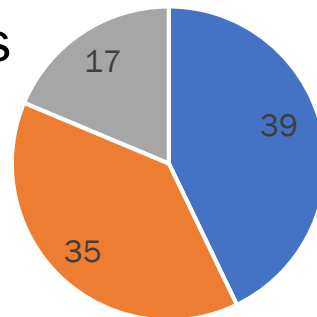


YODA (Yale University Open Data Access) update

- 73 research proposals from 159 trials
- 89% approved, 3% under review, 8% did not proceed
 - Confidentiality
 - Non-availability of specific data elements
 - Proposal not clear



■ In progress ■ Paperwork ■ Submitted ■ Published



■ Secondary research
■ Meta analysis
■ Validation studies



Improving peer review and scientific publication

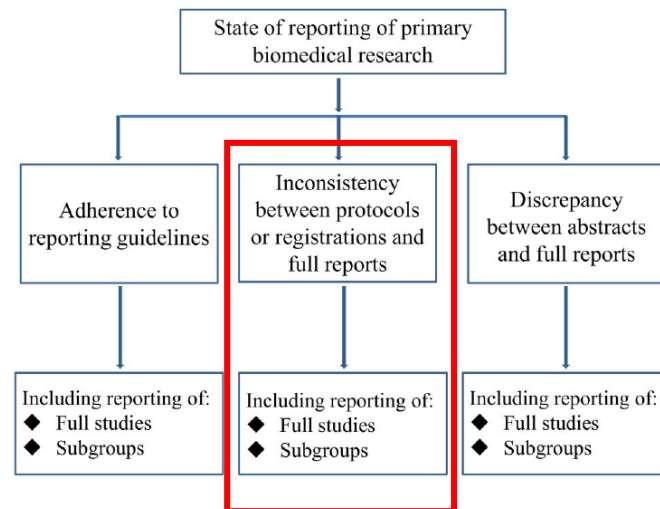
Registration and reporting



Quality of reporting

- COMPARE-style study
- 200 RCT publications
 - Few discrepancies in study design, type or interventions
 - Middling discrepancies in study arms and primary outcome reporting
 - Often discrepancies in start/finish dates, study sponsor, 2° outcomes and data monitoring committees

Li G, et al. BMJ Open 2017;7:e014749.
doi:10.1136/bmjopen-2016-014749





Quality of reporting (cont)



- Non-industry funding associated with lower quality reporting

Have you ever...

- had a peer review challenge specifically on a checklist item?
 - Yes
 - No
 - N/A (not part of my role)



Jackie Marchington @blazingocelots · Sep 11

I can't ever remember a jnl query about a reporting checklist when they've been required in the submission package. Does anyone look? #PRC8

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 11

Questioner suggests better industry reporting is an artefact of more attentive editor/peer review. That would be an interesting study #PRC8

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 11

Non-industry funding associated with lower quality reporting. Spkr speculates could be related to better trained personnel in industry #PRC8

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Jackie Marchington @blazingocelots · Sep 11

Daisy Kosa talking about concordance between trial registry entries and publications. What study characteristics influence rep quality #PRC8

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Optimism bias

- Overestimation of treatment effect sizes (2007–17)
 - Proposed effect size ~25% greater than observed
 - Trials with a statistically significant effect proposed less optimistic effect sizes
 - Compared with 1955–2006, optimism bias has reduced
- Nearly 80% included no rationale for the proposed effect size
- Does failure to establish statistical significance mean we are missing out on incremental clinical improvements?



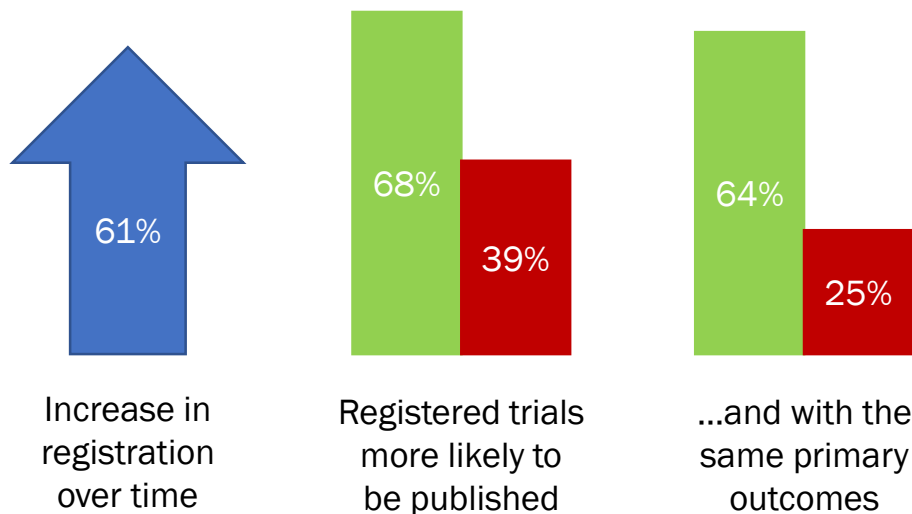
Jackie Marchington @blazingocelots · Sep 11
Optimism bias - only 9.4% of trials had an effect size similar to that hypothesised in the study protocol (2007-17)
#PRC8

[View Tweet activity](#)



Registration and reporting

- Finnish ethics review board study, trial protocols approved in 2002 and 2007



Jackie Marchington @blazingocelots · Sep 11

This study looked at trials approved in Finland in 2002 and 2007. Would love to see 2012 and 2017 to see what changes are happening [#PRC8](#)

[View Tweet activity](#)



Jackie Marchington @blazingocelots · Sep 11

Trial registration is associated with better reporting of trial outcomes [#PRC8](#)

[View Tweet activity](#)



How about industry?

Chan A, Pello A, Kitchen J, Axentiev A, Virtanen JI, Liu A, Hemminki E. Association of Trial Registration With Reporting of Primary Outcomes in Protocols and Publications. *JAMA*. Published online September 11, 2017. doi:10.1001/jama.2017.13001

Table 1. Study Characteristics Associated With Prospective Registration, Publication, and Publication Without Discrepant Primary Outcomes

| Trial Characteristic | Clinical Trials, No. (N = 113) | Registered | | Published ^a | | Published Without Discrepant Primary Outcomes ^b | |
|----------------------|--------------------------------|----------------------|---------------------------|------------------------|---------------------------|--|---------------------------|
| | | No. (%) ^c | AOR (95% CI) ^d | No. (%) ^c | AOR (95% CI) ^d | No. (%) ^c | AOR (95% CI) ^d |
| Sponsor | | | | | | | |
| Industry | 53 | 46 (87) | 1.97 (0.50-7.81) | 36 (68) | 1.23 (0.42-3.61) | 33 (62) | 1.35 (0.47-3.89) |
| Non-industry | 60 | 23 (38) | 1 [Reference] | 28 (47) | 1 [Reference] | 22 (37) | 1 [Reference] |



Jackie Marchington @blazingocelots · Sep 11

Wow, post FDAAA shows 100% registration, 100% results reporting and 98% publication rate [#PRC8](#) for neuropsychiatric medications

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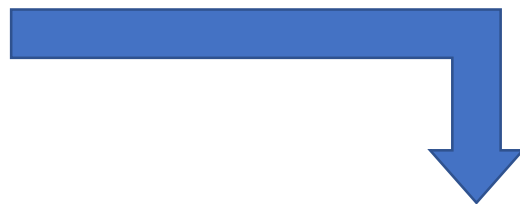
Trial registration is good for results disclosure



A reduction in zombies...



- December 1, 2014, of 329 trials
 - 109 (33%) had results posted on ClinicalTrials.gov only,
 - 42 (13%) available from PubMed only
 - 81 (25%) available from both
 - 97 (29%) in neither



71% of trials have results disclosed



Jackie Marchington @blazingocelots · Sep 11

Q: why are results of publication rate studies so different?
Because they're all looking at different cohorts... [#PRC8](#)

[View Tweet activity](#)



Thank You



Questions

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "**Hosts, Presenters and Panelists.**" Otherwise, **ALL** audience members will be able to see your submitted question



Upcoming ISMPP U's

- November 29, 2017
- Topic: Challenges with Review Articles



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